IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES LISTED IN EXHIBIT A TO MOTION	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF BRIAN J. FLYNN, M.D.

Plaintiffs submit this this Reply in further support of their Motion to Exclude the General Causation Opinions of Brian Flynn, M.D. (Doc. 2130).

INTRODUCTION

Defendant proposes to offer into evidence Dr. Flynn's opinions regarding the safety and efficacy of five different products: TVT-R, TVT-O, TVT-Secur, Prolift and Prolift+M. As discussed in the Motion, Defendant has not met its burden to establish that Dr. Flynn employed a reliable methodology in reaching those opinions. Specifically, Dr. Flynn did not employ a reliable methodology because he systematically ignored all evidence contrary to his opinions. In its Response, Defendant cannot provide even one sentence, from any of Dr. Flynn's five reports, where he discusses or explains why he discounted any of the contrary evidence, because he ignored it. Instead, Defendant misapplies the Court's earlier rulings and erroneously argues that Dr. Flynn's unreliable methodology is not relevant to the *Daubert* inquiry regarding admissibility. *See* Def's. Resp. in Opp. (Doc. 2269) (hereinafter, "Response"). This reliability of Dr. Flynn's methodology is the central focus here, and his unreliable methodology cannot be cured through cross-examination as Defendant suggests.

As shown below and in Plaintiff's Motion, Dr. Flynn should be excluded from offering expert opinions in this case because: (1) he employed an unreliable methodology where he selectively discussed and reviewed one-sided evidence; (2) he never explained why he discounted any of the extensive contrary evidence that he was well aware of; and (3) his personal experience regarding these products is not a reliable basis for his opinions.

In its Response, Defendant admits many of these errors exist. For example, Defendant concedes in its briefing that:

(1) Dr. Flynn purposely chose to only discuss one-sided literature in all five of his reports.

(2) Dr. Flynn did not discuss a single piece of evidence contrary to his opinions in any of his five reports.

(3) Dr. Flynn "didn't have time" to adequately review at a number of important studies that he was aware of and were contrary to his opinions.

(4) Dr. Flynn concluded that he had "read enough" medical literature and would not change his opinions based on any evidence contrary to his opinions.

(5) Dr. Flynn employed the same [unreliable] methodology in all five of his reports.

Dr. Flynn purportedly reached his opinions based upon his review of the medical literature and his personal experience. However, Dr. Flynn cannot simply ask the Court to accept his proposition that he relied upon the literature and his personal experience. He must show that he followed a reliable methodology, which necessarily includes explaining why he disregarded evidence that is contrary to his opinions. Dr. Flynn never discussed any of the contrary evidence in any of his five reports because he only discussed favorable evidence. As the Court has previously explained, this is not a reliable methodology. Accordingly, Dr. Flynn's testimony should be excluded.

ARGUMENT

Dr. Flynn's assertion that his opinions stem from reliance on literature and experience is not dispositive because the Court must also ensure that he "reliably applied" the methodology with the requisite level of intellectual rigor. *See Carlson v. Boston Scientific Corp.*, 2:13-cv-05475, 2015 WL 1931311, at *14 (S.D. W. Va. April 28, 2015). As discussed in this briefing, Dr. Flynn did not reliably apply any methodology to the facts of the case, because he ignored all contrary evidence.

I. WHILE PLAINTIFFS TIMELY FILED THEIR MOTION TO EXCLUDE DR. FLYNN'S TESTIMONY, DEFENDANT IGNORED THE COURT'S RULES REGARDING PAGE LIMITS.

Likely because Defendant realizes Dr. Flynn's unreliable methodology infects all five of his reports, Defendant begins its Response by asserting that Plaintiffs' Motion was untimely. Of course, the filing was timely.[1] However, Defendant argues that Plaintiffs' Motion was untimely because the electronic filing process that was timely initiated on May 5, 2016, did not complete processing of the lengthy exhibits until after midnight EST. As required by the Court, a Memorandum in Support of the Motion (Doc. 2131) was then filed via the electronic filing system immediately after the electronic filing system processed and uploaded approximately 500 pages of exhibits. Defendant cites no authority for its novel interpretation. Likewise, Defendant does not assert that it was prejudiced by the time that lapsed between when the filing process began and when the process completed a few minutes later.

Ironically, in the very brief where Defendant asserts that its novel interpretation of the rules is appropriate, Defendant then disregards the Court's filing requirements. Without seeking prior approval from the Court, Defendant filed a brief exceeding the page limits in Local Rule of

[1] Notice of Electronic Filing (attached as Ex. A to Reply) ("The following transaction was entered by Zonies, Joseph on 5/6/2016 at 0:03 AM EDT and **filed on 5/5/2016**") (emphasis added).

Civil Procedure 7.1(a)(2). Because Defendant has filed a nonconforming brief, Plaintiffs respectfully ask that the Court strike Defendant's Response brief and grant Plaintiffs' timely, unopposed Motion.

II. DR. FLYNN'S OPINIONS ARE THE RESULT OF AN UNRELIABLE METHODOLOGY, INVOLVING A ONE-SIDED REVIEW OF *ONLY* FAVORABLE EVIDENCE AND A COMPLETE DISREGARD OF *ALL* CONTRARY EVIDENCE.

As required by Rule 26, an expert must disclose a report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them…." Fed. R. Civ. P. 26(a)(2)(B)(i). Dr. Flynn has not complied with Rule 26 because none of his reports explain his basis for disregarding the extensive contrary evidence he was aware of. As such, he has not established that he followed a reliable methodology, and his testimony should be excluded.

A. Ethicon Concedes Dr. Flynn Employed a Series of Methodological Flaws When Reviewing the Medical Literature and Science, Including *Only* Discussing One-Sided Evidence and Disregarding *All* Contrary Evidence.

As demonstrated in Plaintiffs' Motion, as Dr. Flynn admitted and Defendant concedes, in his five reports Dr. Flynn only discussed studies that supported his opinions that Ethicon's devices were safe and effective. Flynn 4/14/16 11:52 A.M. 24:13-15 ("I tried to choose articles that supported my opinions….") (attached as Ex. H to Motion). This alone calls into question the reliability of Dr. Flynn's literature review, analysis and, in fact, his entire opinion.

However, critically, when Dr. Flynn was confronted with key contrary studies during his deposition, he had no sound scientific reasoning to support his refusal to credit the studies. Instead, he had excuses akin to a high schooler with missing homework. For example, when asked why he did not address several studies non-supportive of his opinion he testified: "I didn't have time to look at those…." *Id.* at 223:6-224:1. Another time, he testified: "I believe I've read

enough…." Flynn 4/19/16 78:4-8 (attached as Ex. G to Motion). Again, this clearly demonstrates the lack of any scientific method underlying Dr. Flynn's opinions.

Most importantly, however, when Dr. Flynn was asked whether the studies that contradicted his opinions might change his opinions, Dr. Flynn admitted they might. He testified that "[t]hey may have, they may not have" and "[t]here's always possibilities, but I think it's unlikely." Flynn 4/14/16 11:52 A.M. 175:1-6.

Daubert requires that an expert's opinions be derived from a reliable methodology. As the Court has previously noted, an expert must use a reliable methodology when reviewing scientific evidence, including explaining why an expert relies on certain evidence and discounts contrary evidence. Regarding an expert's treatment of contrary evidence, three possible scenarios can exist: (1) an expert may be aware of contrary evidence and simply ignore and not discuss the evidence; (2) an expert may be aware of contrary evidence and explain his reasons for discounting that evidence; and (3) an expert may not be aware of some contrary evidence and therefore not address the evidence in his Rule 26 report.

If an expert's treatment of contrary evidence falls into the first category, where the expert is aware of the contrary evidence but has not explained his reasons for discounting the evidence, the expert has employed an unreliable methodology under the *Daubert* analysis. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *12-13 (S.D. W. Va. Sept. 29, 2014) (excluding testimony of Dr. Margolis for failure to explain why he rejected Nilsson 17-year data that was contrary to his opinions). Without some explanation for disagreement with contrary evidence, an expert's methodology is unreliable. *See Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 676 (S.D. W. Va. 2014) (explaining that an expert's opinion is the result of an unreliable methodology if the expert "fails to account for contrary scientific literature

and instead selectively [chooses] his support from the scientific landscape.") (internal citation and quotation omitted). Here, Dr. Flynn admits, and Defendant concedes, that all five of his reports failed to account for any contrary scientific literature and selectively chose support from the scientific landscape.

If an expert's treatment of contrary evidence falls into the second category, where the expert is aware of the contrary evidence and explains his reasons for discounting the evidence, courts have found that the expert has employed a reliable methodology for purposes of *Daubert*. The testimony is generally admissible, and any flaws in the reasoning for discounting the contrary evidence can be addressed through cross-examination. *See Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, *10 (S.D. W. Va. May 5, 2015) (allowing testimony of Dr. Margolis where he provided in his report and deposition "a sufficiently thorough explanation as to why he discounted certain literature, including discussions of bias in corporate-sponsored studies"). Here, this is not the case because Dr. Flynn did not provide any reasoning in any of his reports for discounting the contrary evidence.

If an expert's treatment of the contrary evidence falls into the third category, where the expert was not aware of the contrary evidence, the expert's methodology is not necessarily unreliable. A court can still find the expert employed a sufficiently reliable methodology for purposes of *Daubert* and admit the testimony. If the court finds the expert's methodology was sufficiently reliable, the overlooked contrary evidence can be addressed through cross-examination. *See Trevino v. Boston Scientific Corp.*, No. 2016 WL 1718836, *41 (S.D. W. Va. Apr. 28, 2016) (noting that "[i]f there are certain device-specific publications that Dr. Badylak **failed to review** in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.") (emphasis added). Here, Dr. Flynn did not simply "fail to

review" some publications. Unlike Dr. Badylak in *Trevino*, Dr. Flynn was aware of the contrary evidence, reviewed the studies, and included them on his reliance list. However, he employed an unreliable methodology because he never explained why he disregarded any of the contrary evidence.

Accordingly, Dr. Flynn's treatment of contrary evidence falls into the first category and demonstrates an unreliable methodology. Defendant misrepresents Plaintiffs' arguments as "nit-picking" Dr. Flynn for "failure to cite certain studies." Response at 7. However, Dr. Flynn's methodological flaws are not limited to simply overlooking a few studies. As discussed in the Motion, Dr. Flynn admitted that he purposely chose to only cite and discuss one-sided evidence, while inexplicably disregarding *all* contrary evidence of which he was well aware. Flynn 4/14/16 11:52 A.M. 24:13-15 ("I tried to choose articles that supported my opinions, so it's more what I use to make my opinions, not what I decided not to use.") .

When further questioned as to the contrary evidence, Dr. Flynn admitted that "he didn't have time" to adequately review contrary evidence that he was aware of. When asked whether a number of studies that were contrary to his opinions met his criteria for whether the evidence was sufficiently important to include in his reports, Dr. Flynn admitted, "I would have to look at them more specifically. **I didn't have time to look at those.** They may have, they may not have." Flynn 4/14/16 11:52 A.M. 223:16-224:1 (emphasis added). Defendant concedes that Dr. Flynn did not have time to adequately review the contrary evidence. A lack of time of time to adequately review the evidence does not justify an unreliable methodology.

Despite conceding that Dr. Flynn did not have time to adequately review the relevant evidence, Defendant erroneously asserts that Dr. Flynn performed an "extraordinarily comprehensive" review. Response at 3. Further, in his depositions Dr. Flynn repeatedly

asserted that he had read "enough" evidence and that it was unlikely any medical literature would change his opinions. Flynn 4/19/16 75:25-76:7; 4/14/16 11:52 A.M. 178:1-6; 4/14/16 11:52 A.M. 178:16-20. Dr. Flynn's assertions that "I've read enough" further demonstrate he did not employ a reliable methodology.

In an attempt to justify Dr. Flynn's selective reliance on one-sided evidence in all five of his reports, Defendant argues that Dr. Flynn's reliance list includes "hundreds of references." Response at 3. Dr. Flynn's inclusion of these articles on his reliance list demonstrates that he was well aware of the contrary evidence. Defendant concedes that Dr. Flynn was well aware of the contrary evidence. Defendant provides no authority for its proposition that Dr. Flynn's one-sided review of favorable evidence is cured by simply listing some contrary evidence on a reliance list. Instead, Rule 26 requires that an expert must disclose in his report all his opinions and his basis for those opinions, including his basis for disregarding contrary evidence.

In its briefing, Defendant attempts to explain *for* Dr. Flynn why he disregarded certain evidence. However, Defendant cannot cite to any explanation from Dr. Flynn's reports for his disregard of the contrary evidence. Defendant argues that Dr. Flynn chose to rely "more heavily on Level 1 evidence," implying that the contrary evidence he disregarded was not Level 1. Response at 5. However, Dr. Flynn also ignored Level 1 evidence. For example, Defendant argues that Dr. Flynn chose to cite to "numerous Cochrane reviews" in his reports. Response at 6. Dr. Flynn testified that Cochrane reviews are "very powerful" Level 1 evidence. Flynn 3/24/16 69:5-7 (attached as Ex. I to Motion). However, as discussed below and in the Motion, Defendant concedes Dr. Flynn ignored Cochrane reviews that were contrary to his opinions, such as the 2014 Nambiar Cochrane review regarding TVT-Secur and the 2016 Maher Cochrane review regarding Prolift and Prolift+M.

Below, Plaintiffs discuss two examples of contrary evidence that was ignored as a result of Dr. Flynn's unreliable methodology. Importantly, these are just two examples of Dr. Flynn's systematic disregard of all contrary evidence, in all five of his Rule 26 reports.

1. Despite being aware of the "very powerful" Level 1 evidence, Defendant concedes Dr. Flynn simply ignored the negative findings from the 2014 Nambiar Cochrane review regarding the TVT-Secur device.

In Dr. Flynn's report regarding the TVT-Secur, he completely ignored Level 1 evidence that was contrary to his opinions. As discussed in Plaintiffs' Motion, the TVT-Secur is a single-incision sling as compared to the multi-incision slings like the TVT-R and TVT-O slings. In his report regarding the TVT-Secur, Dr. Flynn ignored the 2014 Cochrane review by Nambiar specifically addressing the safety and effectiveness of single-incision slings such as the TVT-Secur. The 2014 Nambiar Cochrane review explained that the TVT-Secur was "withdrawn from the market because of poor results." Flynn 3/24/16 72:7-11.

Despite being aware of this powerful contrary evidence, Dr. Flynn has never explained why he discounted its findings. Dr. Flynn included the 2014 Nambiar Cochrane review on his reliance list, and Defendant concedes he was aware of the study. Instead of discussing this powerful Level 1 evidence directly addressing the safety and effectiveness of TVT-Secur, Dr. Flynn selectively cited to evidence that supported his opinions such as a different Cochrane review by Ford *regarding multi-incision slings as opposed to single-incision slings like TVT-Secur* and an older, 2011 review from Wall. Further demonstrating the unreliability of his methodology here, Dr. Flynn even refused to acknowledge that the 2014 Nambiar Cochrane review discussing the TVT-Secur would be more informative when assessing the safety and effectiveness of TVT-Secur, as opposed to a Cochrane review regarding a different type of sling device. Flynn 3/24/16 70:24-71:5.

Defendant concedes Dr. Flynn never explained why he discounted the 2014 Nambiar Cochrane review, which Dr. Flynn testified was very powerful Level 1 evidence. Defendant also concedes that the Ford Cochrane review that Dr. Flynn instead discussed in his TVT-Secur report "may have not been specifically applicable to single incision slings like the TVT-Secur." Response at 8. Dr. Flynn simply disregarded all contrary evidence in his report, including contrary evidence he was aware of and instead selectively cited favorable evidence, even if that evidence was not "applicable" to the product at issue.

2. Despite being aware of the evidence, Defendant concedes Dr. Flynn simply ignored evidence contrary to his opinions regarding Prolift and Prolift+M, including negative findings from Level 1 evidence such as the 2016 Maher Cochrane review regarding mesh based repairs for prolapse.

Similarly, Dr. Flynn was aware of numerous articles that reached conclusions contrary to his opinions regarding the Prolift and Prolift+M devices. Additionally, Defendant admits that Dr. Flynn was aware of the 2016 Maher Cochrane review and explained that "he inadvertently neglected to update his reliance list to include it." Response at 9-10. In contrast to Dr. Flynn's opinions that the Prolift and Prolift+M mesh products are safe and effective for the treatment of pelvic organ prolapse, the 2016 Maher Cochrane review concluded that, "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery [to treat vaginal prolapse]." Flynn 4/14/16 11:52 A.M. 222:8-12. Apparently, Dr. Flynn also "inadvertently neglected to update his" report to explain why he disregarded the findings from the study.

Likewise, Dr. Flynn never explained in his report why he disagreed with the negative findings from other studies that he was aware of, that he included on his reliance list, but that were contrary to his opinions, including the 2012 study by Stanford, the 2010 study by Iglesia, and the 2009 study by Diwadkar. *See* Reliance List (attached as Ex. K to Motion); Memorandum at 10-11. Defendant concedes as much. Dr. Flynn likely did not disclose his basis

for discounting contrary evidence, because he simply disagreed with the conclusions. For example, regarding the 2012 Stanford study that concluded native tissue repairs were as efficacious as mesh repairs for anterior pelvic organ prolapse, Dr. Flynn was asked, "Do you think this study is reliable, or have an opinion one way or the other?" Dr. Flynn responded, "I don't have an opinion. I'm not that familiar with that study." Flynn 4/14/16 11:52 A.M. 104:19-23. This evidence undermines Dr. Flynn's opinion that mesh-based repairs are necessary because alternative procedures such as native tissue repairs are not effective. Plaintiffs still do not know why he discounts this and other contrary evidence, except that the evidence is contrary to his opinions.

It is not Plaintiffs' burden at deposition to present Dr. Flynn with each piece of evidence that is contrary to his opinion. Rather, Rule 26 and *Daubert* require an expert to demonstrate they employed a reliable methodology which includes disclosing his basis for discounting certain evidence in favor of other evidence. Of course, an expert need not discuss in his Rule 26 reports *every* piece of evidence that exists, but Dr. Flynn has not explained his disagreement with *any* of the contrary evidence. Dr. Flynn simply "disagreed" with the studies because they did not support his opinions. This is not a reliable methodology.

B. Dr. Flynn Has Not Established That His Opinions Based on His Personal Experience Are the Product of a Reliable Methodology.

While an expert might be *qualified* through his personal experience to offer expert testimony, he still must establish that he followed a reliable methodology in reaching his opinions. The Court does not have to simply "take his word for it." Here, Dr. Flynn has not disclosed a reliable methodology he used to reach his opinions other than vague, untestable assertions. Additionally, Dr. Flynn does not reconcile his statements from outside of this litigation that are contrary to his opinions here.

In his own practice, he contradicts the opinions he offers here. For example, in his litigation report here, he concludes that the TVT-O is safe and effective for treatment of stress urinary incontinence ("SUI") in women. Yet, he testified that, "Sitting here today with the information and experience I had with both products, no, **there'd be no reason I would use a TVT-O over the TVT-Abbrevo** unless the patient had requested that." Flynn 4/14/16 8:42 A.M. 44:3-6 (attached as Ex. J to Motion). He explained he does not use the TVT-O because the TVT-Abbrevo has less transient leg pain, shorter convalescence, and quicker return to work and normal daily living. *Id.* at 28:22-31:8. Dr. Flynn's litigation opinion that TVT-O is safe and effective is contradicted by his own testimony that now, with the availability of a safer, better product, there is no reason he would use TVT-O. Despite Defendant's argument, Dr. Flynn does not simply have a *preference* for one product over the other – he testified there is now no reason to use the TVT-O at all.

Further, Dr. Flynn's own publications outside of this litigation contradict his litigation-driven opinions here. For example, in his 2013 article discussing his personal experience with surgical management of mesh-related complications, he stated that he has seen "an alarming increase" and an "escalation in the severity" of mesh complications. Flynn 4/14/16 11:52 A.M. 144:3-145:13. Dr. Flynn did not discuss his own paper in any of his reports here. Likewise, Dr. Flynn did not explain how the "alarming increase" and "escalation in severity" of mesh complications affected his opinions here. His failure to explain his own contrary statements – statements made outside of the litigation context -- further indicates he employed an unreliable methodology.

In addition to these unexplained contradictions between his personal experience and his opinions here, Dr. Flynn's "personal experience" with these products is not sufficiently reliable.

Dr. Flynn does not know how often women suffer complications from these mesh devices. For example, when asked how many TVT-Secur products he has revised or explanted, Dr. Flynn admitted he does not know the answer. He testified, "I would be guessing." Flynn 3/24/16 13:11-17. Dr. Flynn has explained that this is because he does not "keep track of what the product was necessarily." Flynn 3/24/16 12:8-15. As such, he does not know how often any of these products are injuring women. Based on his own admissions, Dr. Flynn's "personal experience" is not a reliable basis for his opinions that these products are safe. He is simply "guessing" as to his personal experience regarding the safety of these products.

Dr. Flynn must establish that he employed a reliable methodology regarding his personal experience to reach his opinions here. He has not followed a reliable methodology because he is guessing at his own experience and has failed to explain any of his statements from the published literature that are contrary to his opinions here..

Defendant bears the burden to establish that its expert employed a reliable methodology. Dr. Flynn did not discuss *any* of the contrary evidence in any of his Rule 26 reports. Dr. Flynn has admitted that he purposely chose to only discuss evidence in his reports that supported his opinions, which is an inherently unreliable methodology. Likewise, Dr. Flynn has not established that his opinions based on his personal experience are the product of a reliable methodology. Defendant concedes that Dr. Flynn used the same unreliable methodology for all five of his reports. Defendant has failed to carry its burden to establish that its expert followed a reliable methodology. Accordingly, Dr. Flynn's testimony should be excluded.

III. DR. FLYNN'S OPINIONS ABOUT DEGRADATION, MANUFACTURING PROCESSES, AND THE IFU SHOULD BE EXCLUDED BECAUSE THEY ARE THE PRODUCT OF AN UNRELIABLE METHODOLOGY.

As discussed throughout the Motion and this Reply, Dr. Flynn has failed to use a reliable methodology in reaching his general opinions that Ethicon's devices are safe and effective.

However, should the Court still permit Dr. Flynn to testify on these general opinions, the Court should exclude Dr. Flynn from offering opinions about the characteristics and pathology of polypropylene mesh, the design and manufacturing processes of Ethicon, and the adequacy of warnings provided by Ethicon in the IFU and patient brochures. Dr. Flynn admitted he is not an expert in these areas and he employed an unreliable methodology in reviewing the relevant literature regarding these areas. Additionally, the Court has consistently concluded that a urogynecologist like Dr. Flynn, without additional training or qualifications, is not qualified to testify as to the adequacy of labeling.

A. Defendant Concedes Dr. Flynn Will Not Discuss Degradation at the Molecular Level, From the Perspective of a Polymer Scientist, or in Relation to Ethicon's Design Process.

Dr. Flynn has disclosed several opinions regarding the design of the mesh products here, including its propensity to degrade and injure women. However, Dr. Flynn has testified that he is not an expert in pathology and has not done any lab work, bench testing, or biomechanical scientific research on any of these products. Flynn 10/30/14 139:7-10 (attached as Ex. L to Motion); Flynn 8/29/14 9:15-17 (attached as Ex. M to Motion); Flynn 4/19/16 66:4-7. In its Response, Defendant concedes that Dr. Flynn will not offer opinions about "Ethicon's process for developing products" or degradation "at the molecular level and the equivalent of the opinions of [a] polymer scientist." Response at 14.

Nonetheless, Defendant contends that Dr. Flynn is qualified to offer opinions "focused on clinical aspects of alleged degradation." Response at 14. Generally, and as the Court has previously explained, medical doctors like Dr. Flynn may still be qualified to offer opinions regarding degradation from a clinician's perspective. However, Dr. Flynn has specifically testified that he is not qualified to discuss clinical aspects related to the mesh design. When asked whether infection was related to the mesh design, he testified: "whether that is related to

the design of the meshes, that's something a materials scientist might know. But I'm not familiar with that." Flynn 8/29/14 52:16-25 (attached as Ex. B to Reply). Of course, the potential to cause or potentiate an infection is a serious clinical implication, and Dr. Flynn has admitted that he is not qualified to make that assessment. Flynn 4/19/16 79:8-15 ("I'm uncertain on what the implications of the cracking would be."). Plaintiffs' and Defendant's biomaterials and pathology experts have offered opinions regarding the interplay among mesh design, degradation, infection, and other clinical outcomes. Dr. Flynn has admitted he is not qualified to offer an opinion regarding these issues.

Even if the Court determines Dr. Flynn is qualified, "an analysis of the reliability of that expert's methodology is required." *Sanchez,* 2014 WL 4851989 at *6 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S.579, 597 1993)). "Qualifications alone do not guarantee reliability". *Id.* (internal citation omitted). Dr. Flynn's opinions regarding mesh design, degradation, and clinical outcomes are not the product of a reliable methodology.

In the *Sanchez* case, the Court noted that Dr. Margolis stated in his report that there is a lack of evidence supporting clinical benefits as it relates to POP and SUI polypropylene mesh. Yet, in his deposition, Dr. Margolis then testified that there were studies supporting the use of the polypropylene mesh. *Id.* at *14. The Court stated that "[i]nconsistent statements of a witness may be addressed on cross-examination." *Id*. However, the Court still excluded the testimony by Dr. Margolis because his "inconsistencies seem to directly shed light on the unreliability of his method." *Id.* at *15. Similarly, here, Dr. Flynn's inconsistent statements "shed light on the unreliability of his method."

In his reports, Dr. Flynn stated that he has "never read or seen a single peer-reviewed published article or seen any cited by plaintiffs' experts that showed any clinical effect of

degradation." *See, e.g.*, TVT Report at 27 (attached as Ex. B to Motion); Flynn 4/19/16 75:25-76:7. In his deposition Dr. Flynn was presented with published medical literature that showed "cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation." Flynn 4/19/16 77:4-17. When asked whether he would have liked to have reviewed the article showing clinical effects from degradation prior to writing his report, he responded that he had "read enough articles on degradation." Flynn 4/19/16 75:25-76-7. Dr. Flynn's refusal to review evidence contradicting his opinions directly sheds light on the unreliability of his method, and his testimony should be excluded.

B. Dr. Flynn's Analysis of Laser Cut Mesh (LCM) Is Unsupported, Unreliable, and Contradicted by the Evidence.

Dr. Flynn offers additional opinions that the design and manufacturing process of the mesh, specifically regarding how the mesh is cut, does not have any clinical implications. As discussed above, Dr. Flynn has admitted and Defendant concedes that he is not qualified regarding the materials science or design aspects of the mesh. However, Defendant argues he may potentially be qualified to testify from his personal experience as to the clinical outcomes related to how the mesh was cut. To do so, however, would require Dr. Flynn to establish that he applied a reliable methodology in reaching this opinion. Dr. Flynn has not and cannot do so.

Experts cannot base their opinions on unsupported assumptions. *See Hathaway v. Bazany*, F.3d 312, 318 (5th Cir. 2007). Here, Dr. Flynn makes several unsupported assumptions to reach his opinion that there is no clinical impact from the manufacturing and cutting process. First, he assumes that he can compare devices that were only available in mechanically cut mesh to different devices that were only available in laser cut mesh to establish the safety of completely different products. Next, he assumes certain studies used *only* laser cut *or* mechanically cut mesh. However, he was unable to identify which mesh was used in any

specific study, because such information is not available. Flynn 4/19/16 118:13-119:18. Instead, he incorrectly assumed that all studies after 2006 used only laser cut mesh. In fact, Dr. Flynn does not know how many mechanically cut versus laser cut products he has used. Flynn 4/19/16 136:7-8; Flynn 4/19/16 156:23-157:1.

Without some explanation or basis, he cannot simply assume that it is reliable to compare completely different devices to establish the safety of the products here. Likewise, he cannot simply assume all devices used laser cut mesh after a certain date without some reliable basis. In fact, in deposition, Dr. Flynn was presented with evidence that contradicted his assumption that all products after 2006 used only laser mesh, and he admitted his assumption may be incorrect. When confronted with an internal Ethicon email stating that even after the launch of laser cut mesh 90 percent of the TVT and TVT-O products on the market were still mechanically cut, Dr. Flynn admitted, "That's what it says, and **that may be true**…" Flynn 4/19/16 120:23-121:13.

Dr. Flynn did not follow a reliable methodology in reaching his opinions regarding the safety of the five products here related to the manufacturing processes because he based these opinions on unsupported assumptions. This testimony should be excluded.

C. Dr. Flynn is Unqualified to Offer Opinions Regarding the Adequacy of Ethicon's Warnings.

Dr. Flynn offers numerous opinions regarding the *adequacy* of Ethicon's warnings. While the Court has allowed expert testimony from medical doctors regarding what complications they have seen in their practice and whether those warnings were included on the label, the Court has consistently held that medical doctors are not qualified to opine as to the *adequacy* of warnings without some additional qualifications, for example, regarding the regulatory requirements for a label. *See Trevino*, 2016 WL 1718836, at *45 (holding that "without additional expertise in the specific area of product warnings, a doctor … is not qualified

to opine that a product warning was adequate …").

Dr. Flynn is not qualified to opine as to the regulatory requirements regarding warnings or Ethicon's own internal standards. He admits he is not qualified here, and Defendant concedes as much. Dr. Flynn can testify that certain complications are listed in the label, but he cannot testify as to the adequacy of the label. These opinions should excluded.

D. Dr. Flynn's Impermissible Legal Conclusions Must Be Excluded.

Dr. Flynn offers numerous conclusions regarding the legal issues here. Defendant argues that Dr. Flynn's opinion that Ethicon "adequately warned" is not a legal conclusion. Of course, this is the ultimate issue for the jury to decide. These and other legal opinions should be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (holding that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

CONCLUSION

Dr. Flynn's few general causation opinions should be excluded for the reasons set forth above and in the Motion. Plaintiffs respectfully request that the Court grant Plaintiffs' Motion and exclude the proffered general causation expert testimony of Brian Flynn, M.D.

Respectfully submitted this 30th day of May, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF BRIAN J. FLYNN, M.D.,** on May 30, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Sarah Peasley
Sarah Peasley